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REMARKS / ARGUMENTS

Claims 1-26 remain in the application. Claims 1 and 14 have been amended to further define the nature of the implantable device. Claims 4, 6, 10, 11 and 13 have been amended to address rejections under 35 USC 112. Claims 1, 3-9, 11-14, 16-22 and 24-25 stand rejected under 35 USC 102(e), the Examiner contending that such claims are anticipated by Maschino U.S. Patent 6,600,956. The Examiner contends that Maschino discloses a placement structure having a hollow cavity formed within that is capable of holding and retaining an implantable device within, because the holder elastically expands along its circumference and will stretch to accommodate an implantable device because the size and dimension of the implantable device have not been set forth. Applicant's amended claim 1 and 16 are quite specific in defining "...a holder having a hollow cavity adapted for receiving and holding the implantable device..." (Emphasis added) Accordingly, there is defined as an express limitation, a pre-existing specific and unique structure for receiving and holding the implantable device. Figure 35 along with Figures 25, 26, 27, 32 and 33, for example, clearly illustrate the structure defined by the above noted limitations.

Thus, despite what the Examiner contends, there is simply no structure disclosed in Maschino to support the existence of a pre-existing hollow cavity for receiving and holding an implantable device. The Examiner's comment that a hollow cavity is formed "...because the holder elastically expands along its circumference and will stretch to accommodate an implantable device...", (p. 4, ¶ 9), is both factually incorrect and

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contrary to the express teaching of Maschino, as reinforced by the figures shown in Maschino.

Furthermore, the hollow cavity defined in claims 1 and 16 is pre-existing prior to insertion of the implantable device. Whereas, the Examiner requires that the holder of Maschino, which does not have a pre-existing hollow cavity, first receive an implantable device after which the holder must be elastically stretched and contorted over the implantable device in order to create, what the Examiner contends is a hollow cavity. In other words, the original shape or for that matter, even with contorting the original shape of the device of Maschino, the device simply does not read on the claimed invention. No matter how much the nerve electrode of Maschino is stretched along its circumference, no hollow cavity will be formed to hold and retain an implantable device. That is merely an implausible creation and redesign of Maschino by the Examiner, without a shred of identifiable support in Maschino. The absence of size and dimensions of Applicants' implantable device is completely irrelevant. According to the teachings of Maschino, any elasticity provided by the ties 24 and 25 in the electrode assembly (cuff) 10 is solely to accommodate nerve swelling or tensile forces acting on the electrode structure from the lead (Maschino col. 7, lines 55-57). There is no teaching nor suggestion that the ties 24 and 25 can accommodate more than nerve swelling. Clasps 24 and mating holes 25 act to fasten closed cuff 10 so that relative movement of cuff portions 18A and 18B are severely restrained. Suture 26 provides a fail safe closure of the cuff to prevent the opening of the cuff, if the clasps should become separated from their mating holes (Maschino col. 7, lines 51-55). Stretching of the cuff 10 to accommodate the positioning of an implantable device adjacent a nerve

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independent of its size and dimensions, would leave no space to accommodate the swelling of a nerve, thereby defeating one major objective teaching of Maschino.

With respect to claims 3 and 16, each claim positively recites a hook portion, which is supported in the specification, for example, in paragraph [0118] and in Fig. 29. The Examiner considers the open ends of the end portion of cuff electrodes 34 and 35 at cuff split 17 as the claimed hook portion. The fatal aspect of the Examiner's consideration is that there simply is no hook portion disclosed, shown or even suggested in Maschino. Fig. 3 of Maschino, which the Examiner apparently has reproduced in the Office Action, does not show any hook portion. Maschino describes in several instances, an electrode assembly with a split circumferential configuration (See the Abstract). As defined by the website Wolfram's Math World, a circumference is "the perimeter of a circle", which is very consistent with the electrode assembly 18A and 18B shown in Fig. 3 of Maschino not showing any hooks and renders the Examiner's creative, but impermissible and unsupportable redesign of an express teaching and disclosure as totally contrary and inconsistent with Maschino.

Paragraph 11 of the office action, recites "Maschino, et al. discloses an implantable device is essentially tubular (13 and 14, electrical conductors which Examiner is interpreting as the tubular implantable device)". Here again, the Examiner interprets Maschino contrary to the express teaching of Maschino. Maschino defines elements 13 and 14 as electrical conductors and not medical devices. Maschino further teaches that conductors 13 and 14 may be coupled to a remote electronics package such as a signal generator (See Maschino, col. 6, lines 58-64). Thus Maschino expressly distinguishes between conductors 13 and 14 and a remote electronics

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package (presumably a medical device). It is well recognized that words are given their ordinary and accustomed meaning unless it appears that the inventor used them differently. In this case, Maschino defines conductors 13 and 14 as conductors and not as a medical device, so that the Examiner's interpretation as the subject elements being a tubular implantable device is improper and contrary to the express teachings of Maschino. Furthermore, medical devices are defined by the FDA in 21 CFR 860, whereas electrical conductors are not defined as medical devices by the FDA, still highlighting the Examiner's mischaracterizations. Of course, Maschino expressly teaches away from the Examiner's contention because Maschino teaches a remote package in communication with the nerve electrode rather than the package being held by the nerve electrode.

In paragraph 11, the Examiner further goes on to consider the holder to be capable of expanding along its circumference to accommodate the implantable device. The Examiner's position is inconsistent with a prior interpretation that conductors 13 and 14 are considered the tubular implantable device. Which is it? Furthermore, the assembly of Maschino is designed specifically to expand solely for the purpose of accommodating swelling of inflamed nerves. If as the Examiner contends, the assembly is expected to receive an implantable medical device, then there would be no space to accommodate a swollen nerve or even an unaffected nerve for that matter, which would therefore defeat an express objective of the Maschino teaching and design. Further in paragraph 11, the Examiner concedes that the assembly (holder) is semi-circular and contends that the holder has first and second end plates, referring to Fig. 1A of Maschino. This concession, of course defeats the Examiner's position that

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the assembly includes a hook portion since semi-circular geometries are just that, circular without a hook. If Maschino intended the assembly to include a hook, he would have stated that the assembly has semi-circular portion and a hook portion, which of course he did not. Furthermore, as claimed, the hook portion captures neural / muscular tissue, whereas Maschino teaches clasp 24 and mating hole 25 to fasten closed the cuff on a nerve, rather than a non-existent hook to accomplish such a function. Moreover, the cited Fig. 1A does neither show nor suggest a hook portion.

With regard to claims 6 and 19 discussed in paragraph 11, it has been previously discussed that the assembly of Maschino does not show a hollow cavity nor any structure that at all can be interpreted or considered a hollow cavity. Moreover, there is absolutely no disclosure, suggestion or reference in Maschino (and contrary to the Examiner's contention) to anything that resembles or can even remotely be considered end plates as claimed by Applicants.

With regard to claims 7, 8 and 9, the Examiner contends that the conductive portion is formed to minimize eddy currents referring to Figs. 1 and 3 and col. 4, lines 34-36. This is pure unsupported conjecture on the part of the Examiner. Nowhere in Maschino and in particular to the cited figures and language, is there any reference whatsoever to eddy currents. Nor is the conductor described as being configured for minimizing eddy currents. The Examiner's reference to Figs. 4D-4E to show a comb shaped conductor portion is somewhat baffling. Applicants' conductive portion is shown in Fig. 33 and discussed in paragraph [0121], for example, as having parallel spaced apart conductors that are comb shaped, that is, a plurality of spaced apart conductors terminating at a boundary and so configured to reduce eddy currents. The Examiner

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cannot identify any conductor configuration in Maschino that shows, teaches or suggests a comb shaped conductor pattern for minimizing eddy currents. As is well known, eddy currents are caused by a moving magnetic field intersecting a conductor or vice-versa (See Wikipedia online encyclopedia). Applicants' claimed invention accommodates an implantable medical device which may be recharged using a magnetic field. Accordingly, eddy currents are a consideration and claims 7-9 address those considerations and provide elements or structures to minimize eddy current effects. Maschino does not include an implantable medical device to be held in its disclosed assembly. Accordingly and justifiably, no consideration for eddy current generation is made in Maschino which reinforces and confirms the absence of any conductor arrangement configured to address eddy currents. Accordingly, the Examiner's position has no basis in scientific fact nor is it supported by any teaching in Maschino, whether expressly or inherently.

Lastly, Applicants cannot respond to the examiner's comment that "...where it is inherent that the reference current spread is, in its broadest interpretation, an eddy current because an eddy current is a current that runs contrary to the main current...", since it appears to be a non sequitor. The phrase "reference current spread" has no relationship to eddy currents. Current spread, as it is accepted in the art, defines the path current takes from a source to a sink. One of the aims of the invention of Maschino is to reduce current spread (col. 1, lines 10-11, col. 3, line 63). Maschino cites a prior art electrode assembly which has the disadvantage of wide current spread between the anode and the cathode, which can cause adverse muscle or external tissue stimulation (col. 2, lines 2-5). One of the stated advantages of the invention

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described by Maschino is reduced stimulus current spread to adjacent tissues (col. 5, lines 46-55). A current flowing between a cathode and an anode which spreads out to adjoining tissue, as in Maschino, is a completely different phenomenon compared to Applicants' discussion of an eddy current that could be generated within battery electrodes 222 of Fig. 11, (§ 0106) or within conductive paths 524 and 526 on wings 504 in Fig. 33 (§ 0121) by an external magnetic field. Current spread, in no way refers, even in its broadest interpretation, or any interpretation for that matter, to eddy currents. As was previously discussed, eddy currents are generated as a result of exposure of an electrical conductor to a magnetic field. Thus the examiner has completely misinterpreted the science of eddy currents and current spread.

With regard to the Examiner's comments in paragraph 12, applicant has argued that Maschino simply does not include, teach, show or suggest, either expressly or inherently, a hollow cavity, no matter how tortured the stretch is made. Accordingly, since an expressly recited element of the claim is absent in Maschino, claims 11 and 24 cannot be anticipated. The matter of the Examiner's contention that the wings elastically expand to accommodate an implantable device and a nerve has been priorly discussed, which will not be repeated here and again.

Similarly, for claims 12 and 25 discussed in paragraph 13, the arguments advanced priorly by applicant to rebut the Examiner's contention that the holder expands to accommodate an implantable device is repeated here and again. Accordingly, claim 13 is simply not anticipated by Maschino.

With regard to claim 13 discussed in paragraph 14, the argument advanced priorly by Applicants to rebut the Examiner's contention that the holder includes a

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hollow cavity is repeated here and again. Accordingly, claim 13 is simply not anticipated by Maschino.

With regard to paragraph 16, Applicants wish to thank the Examiner for the advise of obligation under 37 CFR 1.56 in order to test the applicability of 35 USC 103(c). However, the subject matter and claimed invention, at the time the invention was made, were not owned by, nor under an obligation of assignment, to the same person, or under a joint research agreement.

With regard to the rejection of claims 2, 10, 15 and 23 under 35 USC 103(a), that since such claims depend from what applicant considers patentable independent claims, these claims are therefore patentable as well.

In view of the amendments to claims 1, 4, 6, 10, 11, 13 and 14 and the arguments advanced to rebut the Examiner's contentions, applicant considers all the claims in the application in condition for allowance. With regard to the rebuttal arguments, Applicants have repeatedly emphasized that the Examiner has impermissably redesigned the cited reference with hindsight, in order to support the rejection of the claims. The Examiner's redesign is prohibited by the rules governing rejections under 35 USC 102. More specifically, anticipation requires that each and every element of the claimed invention be disclosed in a single prior art reference (See *In re Paulsen* 30 F. 3 rd 1475, Fed. Cir. 1994). Applicant has clearly identified where selected elements in the claimed invention do not exist in the reference, despite the Examiner's attempt to redesign the reference and add non-existent features to the cited reference. Furthermore, there must be no difference between the claimed invention and the reference as viewed by a person of ordinary skill in the field of the invention.

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(See *Scripps Clinic & Res. Found. v. Genentec, Inc.*, 927 F.2d 1542, Fed. Cir. 1991). Applicants have repeatedly identified the differences in the claimed invention and the cited reference, and the absence of such claimed elements in the reference, despite the Examiner's attempt to redesign the reference. In particular, Applicants have shown unequivocally that Maschino does not show a pre-existing hollow cavity as claimed by Applicants.

Applicants have made a diligent effort to place the claims in condition for allowance. However, should there remain unresolved issues that require adverse action, it is respectfully requested that the Examiner telephone Malcolm J. Romano, Applicants' Attorney at Los Angeles, California area telephone 661-702-6812 so that such issues may be resolved as expeditiously as possible.

For these reasons, and in view of the above amendments, this application is now considered to be in condition for allowance and such action is earnestly solicited.

Respectfully Submitted,

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Date

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